USER FEE COLLECTIONS

PDUFA specifies that user fees shall be collected for prescription drug applications and annual fees shall be collected for establishments and products. The statute further specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation and changes in workload.

Under PDUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future years. The balances carried over from year to year are described on page 7.

Table 1 provides totals of user fees collected during the past two fiscal years, and also reflects the amount of open receivables.

TABLE1: PRESCRIPTION DRUG USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2013

FEES COLLECTED	FY 2012	FY 2013
Application Fees	$222,862,167	$245,451,430
Establishment Fees	$241,989,667	$231,013,962
Product Fees	$244,339,450	$215,292,673
TOTAL COLLECTIONS	$709,191,284	$691,758,065
FEES RECEIVABLE		
Application fees	$0	$0
Establishment Fees	$4,268,807	$5,353,792
Product Fees	$1,088,760	$1,475,700
TOTAL RECEIVABLES	$5,357,567	$6,829,492

Numbers may not add due to rounding to the nearest dollar

The receivables for FY 2012 and FY 2013 are from uncollected application, product, and establishment fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 180 days of the debt being outstanding, PSC will turn the debt over to the United States Treasury for further collection efforts.

User fee collections are reported in the year the fee was originally due – referred to as the cohort year. For example, a fee originally due in FY 2012, even if it is received in FY 2013, is attributed to FY 2012 collections. Totals reported for each fiscal year are net of any refunds for the cohort year. FDA issues invoices for product and establishment fees twice a year: in August for fees due on October 1, and in November after the close of the fiscal year for product and establishment fees due that were not previously billed and paid. To ensure the quality of the information provided in the financial report, FDA updates prior year numbers each year. In FY 2013, fees collected for the FY 2012 cohort year increased by $37,245,257 over the $671,946,027, which was reported in the FY 2012 financial report. This increase is due to the collection of receivables after the end of the fiscal year, as well as to the collection of fees submitted in response to the annual “clean-up” invoices sent out after the close of the fiscal year, for product and application fees that were not invoiced at the beginning of the year.